Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Application ID: DV-2025-CR-37548-1
TGA Reference: E25-651558

Zinzino Pty Ltd

Email: specialistconsultant@live.com.au

Attention: Nicholas Mercieca

Subject: Notice under section 9D of the *Therapeutic Goods Act 1989* of the decision to vary ARTG inclusion for the kind of medical device.

ARTG	GMDN code and term	Class
366784	38092 Capillary blood collection set, home-use	Class IIa

As a delegate of the Secretary of the Department of Health, Disability and Ageing (the Secretary), for the purposes of section 9D of the *Therapeutic Goods Act 1989* (the Act), I am writing to inform you that I have made a decision to vary the ARTG entry in relation to the abovementioned medical device.

I have decided to vary the abovementioned ARTG under subsection 9D(3D) of the Act, on the basis that the information provided for this variation does not reduce the quality, safety or performance of the kind of medical device for the purpose for which it is intended to be used.

Therefore, I have varied the following information on **11 February 2026.**

Update product license name:
From:

Zinzino Pty Ltd - Zinzino Balance Test - Home blood collection kit

To:

Zinzino Pty Ltd - Zinzino Blood Collection Kit - Capillary blood collection set, home-use

Sponsors' ongoing regulatory responsibilities

Australian sponsors of medical devices have ongoing regulatory responsibilities that they supply to the Australian market.

The continued inclusion of the devices of the kind in the ARTG is subject to payment of annual charges.

Ongoing monitoring of quality, safety and efficacy

Therapeutic goods on the ARTG are subject to ongoing monitoring of their quality, safety and performance. At any time, the ARTG entry may be selected for a review to verify compliance of the goods with the regulatory requirements.

Legislation

Therapeutic Goods Act 1989
https://www.legislation.gov.au/Series/C2004A03952

Therapeutic Goods (Medical Devices) Regulations 2002
https://www.legislation.gov.au/Series/F2002B00237

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The fee paid for the application is not refundable (https://www.tga.gov.au/how-we-regulate/fees-and-payments/refunds).

Your review rights are attached at Attachment A.

Yours sincerely

Signed electronically in CM / TRIM

Kai Miller
Delegate of the Secretary
Medical Devices Authorisation Branch
Therapeutic Goods Administration

20 February 2026

Attachment A

Review Rights

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website www.tga.gov.au/resources/resource/guidance/guidance-requesting-reconsideration-initial-decision for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

A list of all attachments in the submission, or a table of contents, would also be appreciated, particularly for requests involving a significant number of supporting materials sent in multiple emails.

All requests for reconsideration should be given to the Minister by email:

Email: **'decision.review@health.gov.au'**

Subject: "<**insert name of person/company making request**> - Request for Reconsideration Under Section 60 of the Therapeutic Goods Act 1989"

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "… - Email 1 of 3", "… - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

Subject to the *Administrative Review Tribunal Act 2024* (ART Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Review Tribunal (ART) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the ART or is otherwise overturned or stayed.